

## MEDICATION GUIDE

### COLCRYS™ (KOL-kris)

#### (colchicine, USP) tablets

Read the Medication Guide that comes with COLCRYS before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about COLCRYS when you start taking it and at regular checkups.

#### **What is the most important information I should know about COLCRYS?**

COLCRYS can cause serious side effects or even death if COLCRYS levels are too high in your body. Keep COLCRYS out of the reach of children.

Tell your healthcare provider about all your medical conditions, including if you have kidney or liver problems. Your dose of COLCRYS may need to be changed.

Certain medicines when taken with COLCRYS can cause the levels of COLCRYS to be too high in your body. It is important for you to tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. COLCRYS and other medicines may affect each other causing serious side effects or even death. Do not start taking a new medicine without telling your healthcare provider or pharmacist.

Even medications that you might take for a short period of time, such as antibiotics, can interact with COLCRYS and cause serious side effects or death.

Especially tell your healthcare provider if you take:

- clarithromycin (Biaxin®)
- telithromycin (Ketek®)
- cyclosporine (Neoral®, Gengraf®, Sandimmune®)
- ketoconazole (Nizoral®)
- itraconazole (Sporanox®)
- HIV protease inhibitors
- nefazodone (Serzone®)

This is not a complete list of all the medicines that can interact with COLCRYS. Talk to your healthcare provider or pharmacist to find out if taking COLCRYS with the other medicines you are taking could be dangerous.

Talk to your healthcare provider before taking any new medicine.

COLCRYS is not a pain medicine and it should not be taken to treat pain related to other conditions unless specifically prescribed for those conditions.

**Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.**

### **What is COLCRYS?**

COLCRYS is a prescription medicine used to treat

- gout flares when taken at the first sign of a flare
- familial Mediterranean fever (FMF)

COLCRYS is only for adults with gout flares or FMF and for children age four or older with FMF.

### **Who should not take COLCRYS?**

Do not take COLCRYS if you have liver or kidney problems and you take certain other medicines. Serious side effects, including death, have been reported in these patients even when taken as directed. See “What is the most important information I should know about COLCRYS?”

### **What should I tell my healthcare provider before starting COLCRYS?**

See “What is the most important information I should know about COLCRYS?”

Before you take COLCRYS tell your healthcare provider about all your medical conditions including if you:

- have liver or kidney problems
- are pregnant or plan to become pregnant. It is not known if COLCRYS will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. COLCRYS passes into your breast milk. You and your healthcare provider should decide if you will take COLCRYS or breast-feed. If you take COLCRYS and breast-feed, you should talk to your child’s healthcare provider about how to watch for side effects in your child.

Tell your healthcare provider about all the medicines you take, including ones that you may only be taking for a short time, such as antibiotics. See “What is the most important information I should know about COLCRYS?” Do not start a new medicine without talking to your healthcare provider.

Using COLCRYS with certain other medicines, such as cholesterol-lowering medications and digoxin, can affect each other causing serious side effects. Your healthcare provider may need to change your dose of COLCRYS. Talk to your healthcare provider about whether the medications you are taking might interact with COLCRYS, and what side effects to look for.

### **How should I take COLCRYS?**

- Take COLCRYS exactly as your healthcare provider tells you to take it. **If you are not sure about your dosing**, call your healthcare provider.
- COLCRYS can be taken with or without food.
- If you take too much COLCRYS go to the nearest hospital emergency room right away.
- If you miss a dose of COLCRYS, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- Do not stop taking COLCRYS even if you start to feel better, unless your healthcare provider tells you.
- Your healthcare provider may do blood tests while you take COLCRYS.

### **What should I avoid while taking COLCRYS?**

- Avoid eating grapefruit or drinking grapefruit juice while taking COLCRYS. It can increase your chances of getting serious side effects.

### **What are the possible side effects of COLCRYS?**

COLCRYS can cause serious side effects or even cause death. See “What is the most important information I should know about COLCRYS?”

Get medical help right away, if you have:

- Muscle weakness or pain
- Numbness or tingling in your fingers or toes
- Unusual bleeding or bruising
- Increased infections
- Feel weak or tired
- Pale or gray color to your lips, tongue, or palms of your hands
- Severe diarrhea or vomiting

The most common side effect of COLCRYS is diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of COLCRYS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store COLCRYS?**

- Store COLCRYS at room temperature between 68° and 77° F (20° to 25°C).
- Keep COLCRYS in a tightly closed container.
- Keep COLCRYS out of the light.

**Keep COLCRYS and all medicines out of the reach of children.**

### **General Information about COLCRYS**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COLCRYS for a condition for which it was not prescribed. Do not give COLCRYS to other people, even if they have the same symptoms that you have. It may harm them. This Medication Guide summarizes the most important information about COLCRYS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COLCRYS that is written for healthcare professionals.

For more information, go to [www.COLCRYS.com](http://www.COLCRYS.com) or call 1-888-351-3786.

## What are the ingredients in COLCRYS?

Active Ingredient: Colchicine

Inactive Ingredients: carnauba wax, FD&C blue #2, FD&C red #40, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, sodium starch glycolate, titanium dioxide, and triacetin.

**This Medication Guide has been approved by the U.S. Food and Drug Administration.**

Manufactured for:

AR SCIENTIFIC, INC.

Philadelphia, PA 19124 USA

by:

MUTUAL PHARMACEUTICAL COMPANY, INC.

Philadelphia, PA 19124 USA

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**NDA 22-351**

**COLCRYS™ (colchicine, USP) tablets**

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Philadelphia, PA 19124

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**PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL(S)**

The goal of this REMS is to inform patients of the serious risks associated with the use of COLCRYS™ (colchicine), including the risks of increased susceptibility to colchicine toxicity in patients with renal or hepatic impairment and potential serious drug-drug interactions with colchicine.

**II. REMS ELEMENTS**

**A. Medication Guide**

A Medication Guide will be dispensed with each COLCRYS™ (colchicine, USP) tablets prescription in accordance with 21 CFR 208.24.

In accordance with 21 CFR 208.24(b), Mutual will ensure that the Medication Guide is available for distribution to patients by providing the Medication Guide in sufficient numbers to distributors, packers or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription of COLCRYS™ (colchicine, USP) tablets.

Sufficient numbers of Medication Guides will be included with each COLCRYS™ (colchicine, USP) tablets bottle along with the Prescribing information. Sufficient numbers of Medication Guides will be attached to or provided with each bottle such that one Medication Guide is dispensed with each 30 day supply. Packaging the product literature with the bottles ensures that every patient receives the Medication Guide with each COLCRYS™ (colchicine, USP) tablets prescription.

Mutual will also make the Medication Guide available through use of tear pads or on our website, [www.COLCRYS.com](http://www.COLCRYS.com)

**NDA 22-351COLCRYS™ (colchicine, USP) tablets**

In accordance with 21CFR 208.24 (d), Mutual will include a statement on the container labels for COLCRYS™ (colchicine, USP) tablets to alert pharmacists to dispense the Medication Guide with the product.

**B. Communication Plan**

This REMS for COLCRYS™ (colchicine, USP) tablets does not include a communication plan.

**C. Elements To Assure Safe Use**

This REMS for COLCRYS™ (colchicine, USP) tablets does not include elements to assure safe use.

**D. Implementation System**

Because this REMS for COLCRYS™ (colchicine, USP) tablets does not include elements to assure safe use, an implementation system is not required.

**E. Timetable for Submission of Assessments**

The Timetable for Assessments is as follows:

- 1<sup>st</sup> Assessment: 18 months post approval
- 2<sup>nd</sup> Assessment: 3 years post approval
- 3<sup>rd</sup> Assessment: 7 years post approval.

Mutual will submit the assessments within 60 days of the close of the interval as noted above.